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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/069,586 | 11/14/2002 | Leland W.K. Chung | 9426-023-999 | 3869 |

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| EXAMINER | |
|---|---|
| SCHNIZER, RICHARD A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | |

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/069,586 | CHUNG ET AL. | |
| | Examiner | Art Unit | |
| | Richard Schnizer, Ph. D | 1635 | |

*-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *18 April 2003*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-31* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-12, 13, and 14, drawn to a therapeutic agent comprising an OSN promoter, a delivery vector and a toxic, therapeutic, and/or heterologous coding sequence.

Group 2, claim(s) 13 and 14, drawn to a method of identifying a test compound capable of modulating osteotropic-specific gene expression.

Group 3, claim(s) 16-27, drawn to methods of delivering a toxic, therapeutic, and or heterologous molecule to osteotropic cells, or to cells of an osteotropic-related cancer, comprising delivering to such cells a vector comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, and a nucleic acid encoding the molecule.

Group 4, claim(s) 28 and 29, drawn to methods of promoting bone repair by delivering to an area where bone repair is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence encoding an interferon.

Group 5, claim 29 drawn to methods of promoting bone repair by delivering to an area where bone repair is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence encoding an interleukin.

Group 6, claim 29 drawn to methods of promoting bone repair by delivering to an area where bone repair is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence encoding a colony stimulating factor.

Group 7, claim 29 drawn to methods of promoting bone repair by delivering to an area where bone repair is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence encoding an angiogenic factor.

Group 8, claim 29 drawn to methods of promoting bone repair by delivering to an area where bone repair is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence encoding a growth factor.

Group 9, claim 29 drawn to methods of promoting bone repair by delivering to an area where bone repair is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence encoding a chemokine.

Group 10, claim 29 drawn to methods of promoting bone repair by delivering to an area where bone repair is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence encoding a cytokine inhibitor.

Group 11, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is interferon alpha, beta or gamma.

Group 12, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is tumor necrosis factor.

Group 13, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is GM-CSF.

Group 14, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is G-CSF.

Group 15, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising

an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is M-CSF.

Group 16, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is NAP.

Group 17, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is MCAF.

Group 18, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is RANTES.

Group 19, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is MIP-1a and MIP-1b.

Group 20, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is a complement component.

Group 21, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is a complement component receptor.

Group 22, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is accessory molecule 87.1.

Group 23, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising

an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is accessory molecule 87.2.

Group 24, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is ICAM-1, 2, or 3.

Group 25, claim 31, drawn to methods of modulating immune functions by delivering to an area where modulation of immune function is necessary a polynucleotide comprising an OSN regulatory region sequence or transcriptionally active fragment thereof, a delivery vector, and a therapeutic coding sequence whose gene product is a cytokine receptor.

Claim 28 link(s) inventions 4-10. Claim 30 links inventions 11-25. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 28, or claim 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups 1-25 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
The technical feature that links the inventions is an OSN promoter. However, OSN promoters were known in the prior art. See e.g. Burton et al (US Patent 5,416,017). Because the technical feature that links the claimed inventions does not make a contribution over the prior art, it cannot be a special technical feature under PCT Rule 13.2.
It is noted that when 37 CFR 1.475(b) allows for grouping of different classes of claims> For example, claims to a composition and a first method of using can be grouped together as a single invention. However, because there is no special technical feature linking the classes of invention set forth in this application, Applicant is not entitled to have the different classes of invention grouped together.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at 703-306-3217. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.